

We claim:

1. A composition comprising ibuprofen and diphenhydramine in amounts effective to treat a pain-associated sleep disturbance, wherein the composition is formulated to prevent negative interactions between the diphenhydramine and the ibuprofen.
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2. The composition of claim 1, wherein the sleep disturbance affects sleep duration.
3. The composition of claim 2, wherein the composition is a bilayer tablet.
4. The composition of claim 2, wherein the composition is a bilayer caplet.
5. The composition of claim 2, wherein the composition is a soft gelatin capsule.
- 10 6. The composition of claim 5, wherein the soft gelatin capsule contains polyethylene glycol.
7. The composition of claim 1, wherein the ibuprofen is present in an amount from 50 mg to 800 mg.
8. The composition of claim 1, wherein the ibuprofen is present in an amount of 200
15 mg.
9. The composition of claim 1, wherein the diphenhydramine is present as diphenhydramine HCl or diphenhydramine citrate.
10. The composition of claim 9, wherein the diphenhydramine HCl is present in an amount from 12.5 mg to 50 mg.

11. The composition of claim 9, wherein the diphenhydramine HCl is present in an amount of 25 mg.

12. The composition of claim 9, wherein the diphenhydramine citrate is present in an amount from 19 mg to 38 mg.

5 13. The composition of claim 9, wherein the diphenhydramine citrate is present in an amount of 38 mg.

14. A method of treating a patient suffering from a sleep disturbance comprising administering the composition of claim 1 and allowing the composition to treat the sleep disturbance.

10 15. The method of claim 14, wherein one dose of the composition is administered.

16. The method of claim 14, wherein two doses of the composition are administered concomitantly.

17. The method of claim 14, wherein one dose is administered and a second dose is optionally administered.

15 18. A method of evaluating a compound or composition for the treatment of a pain-associated sleep disturbance, wherein

a) a compound or composition is administered to a patient after oral surgery;

b) the patient is required to go to bed earlier than said patient's usual bedtime; and

c) and the effectiveness of the compound or composition is assessed.

19. The method of claim 18, wherein the effectiveness of the compound or composition in the patient is assessed by evaluating at least one of: sleep latency, SPRID3, cumulative percent asleep at 60 minutes, ease of falling asleep, duration of sleep, global evaluation of sleep, median time to rescue medication, percent of patients requiring rescue medication, global assessment as a pain reliever, global assessment as a sleep aid, PRID 90 minutes, and PRID 60 minutes.

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20. The method of claim 19, wherein the effectiveness of the compound or composition is assessed by evaluating sleep latency, sleep duration, and SPRID3.

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21. The method of claim 19, wherein the patient goes to bed 1 to 6 hours earlier than said patient's usual bedtime.

22. The method of claim 19, wherein the patient goes to bed at least 1 hour earlier than said patient's usual bedtime.

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23. The method of claim 19, wherein the patient goes to bed at least 3 hours earlier than said patient's usual bedtime.

24. The method of claim 19, wherein the patient goes to bed up to 6 hours earlier than said patient's usual bedtime.

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25. The method of claim 19, wherein the patient experiences at least moderate or severe levels of pain before the compound or composition is administered.